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Docket No.: UMY-034  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Mario Stevenson *et al.*

Application No.: 10/722,689

Confirmation No.: 3913

Filed: November 24, 2003

Art Unit: 1635

For: **MODULATION OF HIV REPLICATION BY  
RNA INTERFERENCE**

Examiner: Richard A. Schnizer

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)**

Dear Sir:

In accordance with 37 CFR 1.97, Applicants hereby make of record the following additional documents. A PTO Form SB/08 and a full copy of each of the documents required under 37 CFR 1.98(a)(2) accompany this statement.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicants understand the Examiner will make an independent evaluation of the cited documents.

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In accordance with 37 CFR §1.97(c)(2) and §1.17(p), please charge the \$180.00 submission fee to our Deposit Order Account No. 12-0080. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 12-0080.

Dated: July 16, 2007

DJM/JHV/jcb

Respectfully submitted,

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(Based on PTO 04-07 version)

<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/722,689-Conf. #3913
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				Examiner Name	Richard A. Schnizer
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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1*	US-6,426,073	07-30-2002	Alizon et al.	
	A2*	US-20020086356-A1	07-04-2002	Tuschl et al.	
	A3*	US-20030055020-A1	03-20-2003	Fire et al.	
	A4*	US-20030068821	04-10-2003	Lois-Caballe et al.	
	A5*	US-20030101472-A1	05-29-2003	Baltimore et al.	
	A6*	US-20030124513-A1	07-03-2003	McSwiggen	
	A7*	US-20030175950-A1	09-18-2003	McSwiggen	
	A8*	US-20040192629-A1	09-30-2004	Xu et al.	
	A9*	US-20040229266-A1	11-18-2004	Tuschl et al.	
	A10*	US-20040259248-A1	12-23-2004	Tuschl et al.	
	A11*	US-20050026278-A1	02-03-2005	Tuschl et al.	
	A12*	US-20050181382-A1	08-18-2005	Zamore et al.	
	A13*	US-20050191618-A1	09-01-2005	McSwiggen et al.	
	A14*	US-20050234007-A1	10-20-2005	Tuschl et al.	
	A15*	US-20070003960-A1	01-04-2007	Tuschl et al.	
	A16*	US-20070003963-A1	01-04-2007	Tuschl et al.	
	A17*	US-7,195,916-A1	03-27-2007	Qin et al.	
	A18*	US-20030051263-A1	03-13-2003	Fire et al.	
	A19*	US-20030056235-A1	03-20-2003	Fire et al.	
	A20*	US-20030101471-A1	05-29-2003	Baltimore et al.	
	A21*	US-20030108923-A1	06-12-2003	Tuschl et al.	
	A22*	US-20030157691-A1	08-21-2003	Qin et al.	
	A23*	US-20040006035-A1	01-08-2004	Macejak et al.	
	A24*	US-20040203145-A1	10-14-2004	Zamore et al.	
	A25*	US-20040259247-A1	12-23-2004	Tuschl et al.	
	A26*	US-20050020525-A1	01-27-2005	McSwiggen et al.	
	A27*	US-20050037988-A1	02-17-2005	Zamore et al.	
	A28*	US-20050186586-A1	08-25-2005	Zamore et al.	
	A29*	US-20050234006-A1	10-20-2005	Tuschl et al.	
	A30*	US-20060009402-A1	01-12-2006	Zamore et al.	
	A31*	US-20070003962-A1	01-04-2007	Tuschl et al.	

FOREIGN PATENT DOCUMENTS						
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	B1	WO-02/44321-A2	06-06-2002	Maxplanck-Gesellschaft		
	B2	WO-2004/014933-A1	02-19-2004	University of Massachusetts		
	B3	WO-2004/111191-A2	12-23-2004	University of Massachusetts		
	B4	WO-2004/042027-A2	05-21-2004	University of Massachusetts		

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	B5	WO-01/75164-A2	10-11-2001	Whitehead Institute for Biomedical Research		
	B6	WO-2005/001043-A2	01-06-2005	University of Massachusetts		
	B7	WO-03/006477-A1	01-23-2003	University of Massachusetts		
	B8	WO-03/022052-A1	03-20-2003	California Institute of Technology		
	B9	WO-2003/070193-A2	08-28-2003	Sirna Therapeutics, Inc.		
	B10	WO-03/022228-A2	03-20-2003	California Institute of Technology		
	B11	WO-03/102131-A2	12-11-2003	Sirna Therapeutics, Inc.		
	B12	WO-03/022040-A2	03-20-2003	California Institute of Technology		
	B13	WO-02/097114-A2	12-05-2002	Ribozyme Pharmaceuticals, Inc.		
	B14	WO-2005/019453-A2	03-03-2005	Sirna Therapeutics, Inc.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
	C1	Arteaga, Jose et al., "Choosing CCR5 or Rev siRNA in HIV-1," <i>Nature</i> , Vol. 21:230-31 (2003)				
	C2	Bernstein, Emily et al., "Role for a bidentate ribonuclease in the initiation step of RNA interference," <i>Nature</i> , Vol. 409:363-366 (2001)				
	C3	Billy, Eric et al., "Specific interference with gene expression induced by long, double-stranded RNA in mouse embryonal teratocarcinoma cell lines," <i>PNAS</i> , Vol. 98(25):14428-14433 (2001)				
	C4	Bitko, Vira et al., "An Endoplasmic Reticulum-Specific Stress-Activated Caspase (Caspase-12) is Implicated in the Apoptosis of A549 Epithelial Cells by Respiratory Syncytial Virus," <i>Journal of Cellular Biology</i> , Vol. 80: 441-454 (2001)				
	C5	Bitko, Vira et al., "Phenotypic silencing of cytoplasmic genes using sequence-specific double-stranded short interfering RNA and its application in the reverse genetics of wild type negative-strand RNA," <i>BMC Microbiology</i> , Vol. 1(34): 1-11 (2001)				
	C6	Bowerman, Bruce et al., "A nucleoprotein complex mediates the integration of retroviral DNA," <i>Genes &amp; Development</i> , Vol. 3:469-478 (1989)				
	C7	Brichacek, Beda et al., "Quantitative Competitive RNA PCR for Quantitation of Virion-Associated HIV-1 RNA," <i>Methods</i> , Vol. 12:294-299 (1997)				
	C8	Caplen, Natasha et al., "dsRNA-mediated gene silencing in cultured Drosophila cells: a tissue culture model for the analysis of RNA interference," <i>Gene</i> , Vol. 252:95-105 (2000)				
	C9	Caplen, Natasha et al., "Specific inhibition of gene expression by small double stranded RNAs				

Examiner Signature		Date Considered	
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Sheet	3	of	4	Attorney Docket Number	UMY-034

		in invertebrate and vertebrate systems," <i>PNAS</i> , Vol. 98(17):9742-9747 (2001)	
C10	Coburn, Glen et al., "Potent and Specific Inhibition of Human Immunodeficiency Virus Type 1 Replication by RNA Interference," <i>Journal of Virology</i> , Vol. 76(18):9225-9231 (2002)		
C11	Dornburg, Ralph et al., "HIV-1 Gene Therapy: Promise for the Future," <i>Advances in Pharmacology</i> , Vol. 49:229-261 (2000)		
C12	Elbashir, Sayda et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," <i>Nature</i> , Vol. 411:494-498 (2001)		
C13	Elbashir, Sayda et al., "Functional anatomy of siRNAs for mediating efficient RNAi in <i>Drosophila melanogaster</i> embryo lysate," <i>The EMBO Journal</i> , Vol. 20(23):6877-6888 (2001)		
C14	Elbashir, Sayda et al., "RNA interference is mediated by 21- and 22-nucleotide RNAs," <i>Genes &amp; Development</i> , Vol. 15:188-200 (2001)		
C15	Fire, Andrew et al., "Potent and specific genetic interference by double-stranded RNA in <i>Caenorhabditis elegans</i> ," <i>Nature</i> , Vol. 391:806-811 (1998)		
C16	Hammond, Scott et al., "An RNA-directed nuclease mediates post-transcriptional gene silencing in <i>Drosophila</i> cells," <i>Nature</i> , Vol. 404:293-296 (2000)		
C17	Hutvagner, György et al., "RNAi: nature abhors a double-strand," <i>Current Opinion in Genetics &amp; Development</i> , Vol. 12:225-232 (2002)		
C18	Ketting, René et al., "mut-7 of <i>C. elegans</i> , Required for Transposon Silencing and RNA Interference, Is a Homolog of Werner Syndrome Helicase and RNaseD," <i>Cell</i> , Vol. 99:133-141 (1999)		
C19	Kimpton, Jaculyn et al., "Detection of Replication-Competent and Pseudotyped Human Immunodeficiency Virus with a Sensitive Cell Line on the Basis of Activation of an Integrated $\beta$ -Galactosidase Gene," <i>Journal of Virology</i> , Vol. 66(4):2232-2239 (1992)		
C20	Li, Yuexia et al., "Molecular Characterization of Human Immunodeficiency Virus Type 1 Cloned Directly from Uncultured Human Brain Tissue: Identification of Replication-Competent and -Defective Viral Genomes," <i>Journal of Virology</i> , Vol. 65(8):3973-3985 (1991)		
C21	Moore, John et al., "New Targets for Inhibitors of HIV-1 Replication," <i>Nature</i> , Vol. 1:40-49 (2000)		
C22	Nykänen, Antti et al., "ATP Requirements and Small Interfering RNA Structure in the RNA Interference Pathway," <i>Cell</i> , Vol. 107:309-321 (2001)		
C23	Paddison, Patrick et al., "Stable suppression of gene expression by RNAi in mammalian cells," <i>PNAS</i> , Vol. 99(3):1443-1448 (2002)		
C24	Sharkey, Mark et al., "Persistence of episomal HIV-1 infection intermediates in patients on highly active anti-retroviral therapy," <i>Nature Medicine</i> , Vol. 6(1):76-81 (2000)		
C25	Sharp, J.G. et al., "Oligonucleotide Enhanced Cytotoxicity of Idarubicin for Lymphoma Cells," <i>Leukemia and Lymphoma</i> , Vol. 42:417-427 (2001)		
C26	Sharp, Philip. "RNA interference-2001," <i>Genes and Development</i> , Vol. 15:485-490 (2001)		
C27	Tabara, Hiroaki et al., "The <i>rde-1</i> Gene, RNA Interference and Transposon Silencing in <i>C. elegans</i> ," <i>Cell</i> , Vol. 99:123-132 (1999)		
C28	Ui-Tei, Kumiko et al., "Sensitive assay of RNA interference in <i>Drosophila</i> and Chinese hamster cultured cells using firefly luciferase gene as target," <i>FEBS Letters</i> , Vol. 479:79-82 (2000)		
C29	Wang, Ming-Bo et al., "High-efficiency silencing of a $\beta$ -glucuronidase gene in rice is correlated with repetitive transgene structure but is independent of DNA methylation," <i>Plant Molecular Biology</i> , Vol. 43:67-82 (2000)		

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Sheet	4	of	4	Attorney Docket Number	UMY-034

	C30	Welker, Reinhold et al., "Virion Incorporation of Human Immunodeficiency Virus Type 1 Nef Is Mediated by a Bipartite Membrane-Targeting Signal: Analysis of Its Role in Enhancement of Viral Infectivity," <i>Journal of Virology</i> , Vol. 72(11):8833-8840 (1998)	
	C31	Wesley, S. Varsha et al., "Construct design for efficient, effective and high-throughput gene silencing in plants," <i>The Plant Journal</i> , Vol. 27(6):581-590 (2001)	
	C32	Yang, Shicheng et al., "Specific Double-Stranded RNA Interference in Undifferentiated Mouse Embryonic Stem Cells," <i>Molecular and Cellular Biology</i> , Vol. 21(22):7807-7816 (2001)	
	C33	Zamore, Phillip et al., "RNAi: Double-Stranded RNA Directs the ATP-Dependent Cleavage of mRNA at 21 to 23 Nucleotide Intervals," <i>Cell</i> , Vol. 101:25-33 (2000)	
	C34	International Search Report for Application No. PCT/US03/37860 dated 7/21/2005	
	C35	Written Opinion for Application No. PCT/US03/37860 dated 5/31/2007	

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